Practitioner's Docket No. 2245/107

CHAPTER II

Preliminary Classification:

Proposed Class:

Subclass:

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

PCT/GB00/02017	05 June 2000 (5.06.00)	05 June 1999 (5.06.99)
International Application Number	**International Filing Date**	**International Earliest Priority Date**

TITLE OF INVENTION: Moisture Resistant Inhaler
APPLICANT(S): Braithwaite, Philip

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ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. SECTION 1.10*
*(Express Mail label number is **mandatory**.)*
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I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date December 5, 2001, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL603053423US, addressed to the: Commissioner for Patents, u.s. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, Box PCT, Attention: EO/US.

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1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. Section 371:

a. This express request to immediately begin national examination procedures (35 U.S.C. Section 371(f)).

b. The U.S. National Fee (35 U.S.C. Section 371(c)(1)) and other fees (37 C.F.R. Section 1.492) as indicated below:

2. Fees

CLAIMS FEE*	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALC-ULATIONS
	TOTAL CLAIMS	25 -20 =	5	x $18.00 =	$90.00
	INDEPEN-DENT CLAIMS	5 - 3 =	2	x $84.00 =	$168.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + $270.00				$0.00
BASIC FEE	U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in Section 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in Section 1.445(a)(2) to the U.S. PTO: where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. Section 1.492(a)(5)) $890.00				$890.00
	Total of above Calculations				= $1,148.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed. (note 37 CFR Sections 1.9, 1.27, 1.28)				
	Subtotal				$1,148.00
	Total National Fee				$1,148.00
	Fee for recording the enclosed assignment document $40.00 (37 C.F.R. Section 1.21(h)). See attached "ASSIGNMENT COVER SHEET".				$0.00
TOTAL	Total Fees enclosed				$1,148.00

*See attached Preliminary Amendment Reducing the Number of Claims.

A check in the amount of $1,184.00 to cover the above fees is enclosed.

3. A copy of the International application as filed (35 U.S.C. Section 371(c)(2)) has been transmitted by the International Bureau.

Date of mailing of the application (from form PCT/IB/308): 14 December 2000

4. A translation of the International application into the English language (35 U.S.C. Section 371(c)(2)) is not required as the application was filed in English.

5. Amendments to the claims of the International application under PCT Rule 66.3 filed in Response to a Written Opinion have been transmitted by the International Bureau.

Date of mailing of the amendment : 14 December 2000

6. A translation of the amendments to the claims is not required as the amendments were made in the English language.

7. A copy of the international examination report (PCT/IPEA/409) is transmitted herewith.

8. Annex(es) to the international preliminary examination report is/are transmitted herewith.

9. A translation of the annexes to the international preliminary examination report is not required as the annexes are in the English language.

10. An oath or declaration of the inventor (35 U.S.C. Section 371(c)(4)) complying with 35 U.S.C. Section 115 is submitted herewith, and such oath or declaration is attached to the application.

II. Other document(s) or information included:

11. An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a) will be transmitted promptly upon request.

12. An Information Disclosure Statement under 37 C.F.R. Sections 1.97 and 1.98 will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. Section 371(c).

13. Additional documents:

a. International Publication No. WO00/74754

Specification, claims and drawing

b. Return postcard

14. The above items are being transmitted before 30 months from any claimed priority date.

AUTHORIZATION TO CHARGE ADDITIONAL FEES

The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No.: 19-4972

37 C.F.R. Section 1.492(a)(1), (2), (3), and (4) (filing fees)

37 C.F.R. Section 1.492(b), (c), and (d) (presentation of extra claims)

37 C.F.R. Section 1.17 (application processing fees)

37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a))

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(54) Title: DELIVERY SYSTEM

(57) Abstract: There is described a medicament delivery device which comprises a medicament reservoir, a medicament delivery passage and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the delivery passage characterised in that the device is provided with a moisture proof barrier. The medicament delivery device is especially suited for use as an inhaler. There is therefore also decribed an inhaler which provides improved airflow for the dispersion of medicament, and a method of treating patients suffering from a respiratory disorder.

Delivery System

This invention relates to a novel form of medicament delivery system and to novel methods of treatment.

In particular the invention provides a medicament delivery device, such as an inhaler, which is adapted to be moisture resistant and/or provides improved air flow through the device.

It is well established that delivery devices adapted for the delivery of dry powder medicaments suffer from the problem of contact with moisture. Such problems are particularly when hygroscopic medicaments are used or when climatic conditions give rise to high humidity. Medicament inhalers are known to suffer from such and moisture contamination of dry powder inhalers has long been held to be undesirable since the dry powder medicament may become clogged, creating problems in delivering correct dosages of medicament. Furthermore, some inhaled medicaments are themselves inherently moisture sensitive. Therefore, there has long been a desire to provide a dry powder inhaler that is resistant to moisture, that is, one that protects a medicament reservoir from moisture contamination either from the environment or from exhalation by a patient using the device and various attempts have been made to mitigate the problem.

Most attempts which have been made aim to reduce the moisture which comes into contact with a medicament, such attempts generally comprise the use of an additional chamber containing a desiccant.

International Patent Application No WO 98/41261 describes an inhalation device which includes a chamber for containing a desiccant, e.g. silica gel. Whilst the use of a desiccant gel does remove some moisture, the system is disadvantageous in that, *inter alia*, the leak paths are too great for the available desiccant to cope with and

therefore the desiccant is only effective for a few hours, whereas there is a need for moisture resistance if at least a few months.

Similarly, International Patent Application No WO 96/08284 describes an inhaler system provided with a reservoir wherein the closed end of the reservoir is also provided with a desiccant cartridge.

International Patent Application No WO 95/32752 also describes a medicament chamber included in an inhalation apparatus and provided with a container containing a desiccant.

European Patent Application No. EP 0520 440, Ambrosio et al, describes a dry powder inhaler which includes a moisture resistant barrier in the form of a flap which is designed to prevent exhaled air from a patient contaminating the medicament held in the reservoir.

US Patent No. 3,854,626, Krechmar et al, describes a pill dispensing system which comprises a moveable mechanism which prevents the ingress of moisture whilst permitting the dispensing of one or more pills.

We have now developed a medicament delivery device, e.g. a dry powder inhaler, which is able to provide a moisture proof barrier without the necessity of a desiccant.

Therefore, according to the invention we provide a medicament delivery device which comprises a medicament reservoir, a medicament delivery passage and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the delivery passage characterised in that the device is provided with a moisture proof barrier.

The moisture proof barrier is preferentially a physical barrier as opposed to a chemical barrier, e.g. a desiccant, although it is within the scope of the present

invention that a desiccant may be included in addition to the moisture proof barrier if desirable.

In a preferred embodiment the moisture proof barrier is positioned so as to prevent the ingress of moisture into the medicament reservoir, so that moisture is prevented from coming into contact with the medicament. In an especially preferred embodiment of the delivery device of the invention, the moisture proof barrier is a moisture proof sealing means.

In a preferred embodiment, the sealing means of the delivery device will operate by the delivery device being adapted to move from an inoperable position, in which the medicament reservoir is sealed, to an operative position, in which the seal is reversibly broken so that measurement and/or delivery of a dose of medicament may take place. The sealing means will generally comprise a resilient sealing member positioned at the end of the reservoir adjacent the metering member. Furthermore, the metering member is preferentially biased towards the resilient sealing member to improve the seal provided. Preferably the resilient sealing member is in a fixed position whilst the metering member moves from an inoperable to an operable position and thus from a sealing to a non-sealing position.

The resilient sealing member preferably comprises a cover adapted to fit the base of the medicament reservoir, the sealing member being provided with an aperture to permit transmission of the medicament. The resilient sealing member may comprise any conventionally known material, for example a natural or synthetic rubber, a silicon or a PTFE material, although other similar materials can be contemplated within the scope of this invention

The moisture proof barrier of the invention may be applied to any conventionally known medicament delivery system. However, in a preferred embodiment, the medicament delivery device is an inhaler. Whilst the moisture proof barrier may be applied to any conventionally known inhaler, it is an especially preferred aspect of the invention for the inhaler to be a dry powder inhaler (DPI). DPI's are known which operate with predetermined doses of medicament, for example, the medicament may be contained in a gelatin capsule which is ruptured to release the medicament. However, a preferred inhaler of the invention is a DPI which comprises a medicament reservoir a metering member which is adapted to measure a selected amount of medicament for inhalation. Thus, in an especially preferred embodiment the metering member is rotatable from an operable to an inoperable position. The metering member may comprise a dispensing member and a moisture resistant member, e.g. a moisture resistant sleeve. In such an embodiment the moisture

resistant member is provided with one or more measuring chambers adapted to measure a predetermined dosage of medicament. Thus, in the operable position, the position of measuring chamber of the metering member corresponds with the aperture in the resilient sealing member so that medicament enters the measuring chamber. The moisture resistant member may then be rotated so that the reservoir is sealed again by the wall of the moisture resistant member. At the same time the medicament is transferred from the measuring chamber of the moisture resistant sleeve to the dispensing chamber of the dispensing member

An example of a preferred DPI is CLICKHALER, produced by Innovata Biomed in the UK. Such a device is described in European Patent No 0 539 469. Thus, the metering member may be a frusto conical member such as described in European Patent No 0 539 469.

Therefore, the metering member may comprise a frusto conical dispensing member with a corresponding moisture resistant sleeve, such that the sleeve overlies the dispensing member. Thus, the measuring chamber may comprise outer side walls which are provided by an aperture in the wall of the moisture resistant sleeve and the base of the measuring chamber may be provided by the frutso conical wall of the dispensing member. Preferably the moisture resistant sleeve is provided with a plurality of apertures and thereby a plurality of measuring chambers.

The use of the frusto-conical shape in the wall of the metering member containing the measuring chambers allows a good seal to be obtained between the metering member and a seat against which the frusto-conical wall mates.

Therefore, the frusto conical metering member may itself comprise a combination of a frusto conical dispensing member and a frusto conical moisture resistant sleeve which forms a snug fit over the dispensing member. The moisture resistant sleeve may itself be moveable eg rotatable, from a sealing to a non-sealing position as herein before described and vice versa. Such a moisture resistant sleeve may

comprise any conventionally known material but is preferentially a plastics material, e.g. the same material as the metering member.

The dispensing member and the moisture resistant sleeve can, preferentially, be adapted so as to act together as a medicament measuring/dispensing member. The preferred metering member comprises a dispensing member provided with one or more dispensing cups and a moisture resistant sleeve provided with one or more apertures. Preferably the dispensing member comprises a plurality of dispensing cups and the sleeve comprises a plurality of apertures. It is especially preferred that the dispensing member comprises an equivalent number of dispensing cups to apertures in the sleeve.

We have especially found that if the moisture resistant sleeve comprises a frusto hemispherical cone, then an improved seal is achieved between the medicament reservoir and the sleeve. When a frusto hemispherical cone sleeve is used, the arcuate base of the reservoir is able to make more uniform contact with the curved surface of the cone and therefore an improved seal is achieved. Thus, it is especially preferred that the outer walls of the cone which are hemispherical. Furthermore, the inner walls of the cone are preferably contoured to form a good mate with the frusto conical dispensing member.

Thus, in operation, the metering member may be moved to a first position in which the medicament is transferred to a first measuring chamber in the moisture resistant sleeve, the device is then moved to a second position in which medicament is transferred from the measuring chamber to a dispensing cup in the dispensing member and then to a third position where medicament is delivered to the delivery passage.

The dispensing member may be a conventionally known member such as a frusto conical member described herein and in EP 0 539 469. However, we have also found the use of a moisture resistant sleeve permits a dispensing chamber to be provided

with an air inlet, e.g. an air duct. Previously, the use of an air inlet was felt to be undesirable since it might effect the accuracy of the measurement of the medicament dose. However, by use of a system wherein the medicament is first transferred to a measuring chamber and then subsequently to a dispensing cup, the cup in the dispensing member may be provided with an air inlet without any loss in accuracy of the dosage delivered. Furthermore, improved air flow provides greater likelihood of complete emptying of the dispensing cup and thereby provide an inhaler with improved performance. Clearly, an inhaler with such improved performance is advantageous per se, regardless of whether such an inhaler is moisture resistant.

Thus according to an alternative feature of the invention we provide a dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the metering member comprises a measuring member adapted to measure a pre-defined dosage of medicament and moveable from a measuring to a non-measuring position; and a dispensing member adapted to receive the measured dosage of medicament from the measuring member and to deliver the medicament to the inhalation passage, the dispensing member being moveable from a medicament receiving position to a medicament delivering position.

In the preferred embodiment the dispensing member is provided with one or more medicament dispensing cups, said cups being provided with a duct so as to provide a flow of air through the cup and into the inhalation passage upon operation of the device.

By the term dry powder we mean a medicament in finely divided form.

A variety of medicaments may be administered by using the inhaler of the invention, optionally with a conventionally known pharmaceutically acceptable adjuvant, diluent or carrier. Such medicaments are generally antibiotics, bronchodilators or

other anti-asthma drugs. Such medicaments include, but are not limited to β_2-agonists, e.g. fenoterol, formoterol, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol and terbutaline; non-selective beta-stimulants such as isoprenaline; xanthine bronchodilators, e.g. theophylline, aminophylline and choline theophyllinate; anticholinergics, e.g. ipratropium bromide; mast cell stabilisers, e.g. sodium cromoglycate and ketotifen; bronchial anti-inflammatory agents, e.g. nedocromil sodium; and steroids, e.g. beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations thereof.

Specific combinations of medicaments which may be mentioned include combinations of steroids, such as, beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations of to β_2-agonists, such as, formoterol and salmeterol. It is also within the scope of this invention to include combinations of one or more of the aforementioned steroids with one or more of the aforementioned β_2-agonists.

The inhaler of the invention is especially suitable for use in the treatment or alleviation of respiratory disorders. Thus according to the invention we also provide a method of administering a dry powder inhalation medicament using an inhaler as hereinbefore described.

We further provide a method of treatment of a patient with a respiratory disorder which comprises the administration of a combination of medicaments using an inhaler as hereinbefore described.

The invention will now be described by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a perspective view of an inhalation device of the invention;

Figure 2 is a schematic representation of the sealing and measuring mechanism.

Figure 3 is a perspective view of a moisture resistant sleeve comprising a frusto hemispherical cone, and

Figure 4 is a cross-sectional view of a moisture resistant sleeve comprising a frusto hemispherical cone.

With reference to Fig 1, a dry powder inhaler (1) comprises a medicament reservoir (2) comprising an essentially conical member; an inhalation passage (3) and a metering member (4). The inhalation passage (3) is connected to the medicament reservoir (2) by a reservoir support (5) and is itself connected to recess (6) which provides a seat for the metering member (4). The metering member (4) is rotatable about an axis (7) from a medicament receiving position, to a medicament delivery position and then to an emptying position to allowing any residual medicament to be emptied into a waste box (8).

The recess (6) is essentially frusto conical in shape to enable it to provide a seal for the metering member (4). The metering member (4) comprises a frusto conical moisture resistant sleeve (9) which forms a snug fit between recess (6) and a dispensing member (10). The dispensing member (10) is also provided with a back plate (11).

The moisture resistant sleeve (9) abuts against the resilient seal (9a) to form a moisture resistant seal.

The moisture resistant sleeve (9) is also provided with a plurality of measuring chambers which comprise apertures (12) dimensioned to measure a predetermined amount of medicament and to fit over cups (13) in the dispensing member (10). In a preferred embodiment, each of the cups (13) are also provided with a duct (14). The medicament reservoir (2) is also provided with a moisture resistant, eg foil, cover (15) at it's end (16) distal from the metering member (4).

With reference to Figure 2, in which Figure 2a the metering device is in a closed position,

Figure 2b the metering device is in a measuring position,

Figure 2c the metering device is in a seal transitory position,

Figure 2d the metering device is in a medicament transfer position,

Figure 2e the metering device is in a medicament delivery position; and

Figure 2f the metering device is returned to the closed position.

In Figure 2a the metering device 4 is in the closed position and the medicament reservoir (2) is isolated and a seal formed between the sealing member (17) and the surface (18) of the moisture resistant sleeve (9). In Figure 2b, the moisture resistant sleeve (9) is rotated in an anti clockwise direction so that the aperture (12) corresponds with the aperture/measuring chamber (19) in the sealing member (17). The aperture/measuring chamber (19) forms a cup with the surface (20) of the dispensing member (10).

In Figure 2c the moisture resistant sleeve (9) is further rotated so that the aperture/measuring chamber (19) sits below the sealing member (17). The internal edge (21) of the sealing member (17) scrapes any excess medicament from the aperture/measuring chamber (19) to leave a measured dose.

In Figure 2d the dispensing member (10) is rotated in an anticlockwise direction so that the dispensing cup (13) corresponds with the aperture (12) allowing medicament to transfer from the aperture (12) to the dispensing cup (13).

In Figure 2e both the dispensing member (10) and the moisture resistant sleeve (9) are rotated anticlockwise to expose them and the medicament to the inhalation passage (3). The patient can then inhale the medicament.

In Figure 2f the inhalation device remains in the closed position ready for use.

With reference to Figures 3 and 4, a moisture resistant sleeve (9) comprises a frusto hemispherical cone (22) wherein the outer surface (23) is arcuate. The inner surface (24) acts as a female member to form a snug fit with the frusto conical dispensing member (10). Downward pressure in the medicament reservoir (2) ensures a constant moisture tight seal between the sealing member (17) and the frusto hemispherical cone (22). Furthermore, referring to Figure 4c, the leading edge (25) of the sealing member (17) is capable of acting as a scraper or a cleaning edge, removing any excess medicament from the measuring chamber upon rotation of the metering member.

A variety of mechanisms may be used for the operation of the inhaler. One preferred mechanism is for movement from the closed to the measuring position to be achieved by removal of a mouth piece which is operably linked to the moisture resistor. Movement from the measuring position to the transitory position would use a mechanism similar to that described in EP 0 539 469, e.g. by depressing the button half way. Movement to the transfer position being achieved by further depressing the button, and then depression completely, moving the metering cone and the moisture resistor to the delivery position.

REVISED CLAIMS FOR INTERNATIONAL PATENT APPLICATION NO. PCT/GB00/02017

1. A medicament delivery device (1) which comprises a medicament reservoir (2), a medicament delivery passage (3) and a metering member (4) adapted to transfer a measured dose of medicament from the medicament reservoir (2) to the delivery passage (3), the device (1) being provided with a moisture proof barrier (9) characterised in that the moisture proof barrier (9) comprises a resilient sealing member in a fixed position.

2. A medicament delivery device (1) according to Claim 1 characterised in that the moisture proof barrier is a moisture proof (9) sealing means.

3. A medicament delivery device (1) according to claim 1 characterised in that the moisture proof barrier (9) is positioned to prevent ingress of moisture into the medicament reservoir (2).

4. A medicament delivery device (1) according to Claim 1 wherein the sealing means is adapted to move from an inoperable position in which the medicament reservoir (2) is sealed, to an operable position in which the seal is broken so that measurement and/or delivery of a dose of medicament may take place.

5. A medicament delivery device (1) according to Claim 1 wherein the sealing means comprises a resilient sealing member positioned at the end of the medicament reservoir (2) adjacent the metering member (4).

6. A medicament delivery device according to Claim 5 wherein the metering member (4) is biased towards the sealing member (9).

7. A medicament delivery device (1) according to claim 1 characterised in that the delivery device is an inhaler.

8. A medicament delivery device (1) according to claim 7 characterised in that the inhaler is a dry powder inhaler.

9. A medicament delivery device (1) according to Claim 4 characterised in that the metering member (4) is rotatable from an operable to an inoperable position.

10. A medicament delivery device (1) according to Claim 1 characterised in that the metering member (4) comprises a combination of a dispensing member (10) and an outer sleeve.

11. A medicament delivery device (1) according to Claim 10 characterised in that the outer sleeve is a moisture resistant sleeve (9).

12. A medicament delivery device (1) according to Claim 11 characterised in that the moisture resistant sleeve (9) is adapted to act as a medicament measuring device.

13. A medicament delivery device (1) according to claim 12 wherein the moisture resistant sleeve is a frusto hemispherical cone (22).

14. A medicament delivery device (1) according to Claim 1 characterised in that the device may be moved to a first position in which the medicament is transferred to a measuring chamber, the device is then moved to a second position in which medicament is transferred to a dispensing chamber and to a third position where medicament is delivered into the delivery passage (3).

15. A medicament delivery device (1) which is an inhaler and comprises a medicament reservoir (2), an inhalation passage (3) and a metering member (4) provided with at least one dispensing cup (13) and adapted to transfer a measured dose of medicament from the medicament reservoir (2) to the

inhalation passage (3) characterised in that the dispensing cup (13) is provided with an air duct (14).

16. An inhaler according to Claim 15 characterised in that the device is provided with a moisture proof barrier.

17. An inhaler comprising a medicament reservoir (2), an inhalation passage (3) for the delivery of the medicament and a metering member (4) adapted to transfer a measured dose of medicament from the medicament reservoir (2) to the inhalation passage (3) characterised in that the metering member (4) comprises a measuring member adapted to measure a pre-defined dosage of medicament and moveable from a measuring to a non-measuring position; and a dispensing member adapted to receive the measured dosage of medicament from the measuring member and to deliver the medicament to the inhalation passage, the dispensing member being moveable from a medicament receiving position to a medicament delivering position.

18. An inhaler according to Claim 17 wherein the second member is provided with one or more medicament receiving cups, said cups being provided with an air duct so as to provide a flow of air through the passage and the cup into the inhalation passage upon operation of the device.

19. An inhaler comprising a medicament reservoir (2), an inhalation passage (3) for the delivery of the medicament and a metering member (4) adapted to transfer a measured dose of medicament from the medicament reservoir (2) characterised in that the metering member (4) is provided with a duct (14) to allow air to be sucked through the metering member upon inhalation by a patient.

20. An inhaler according to claim 19 characterised in that the metering member (4) comprises an outer sleeve and a dispensing member (10).

AMENDED SHEET

21. A medicament delivery device (1) according to claim 20 characterised in that the duct is part of a measuring cup in the dispensing member.

22. A method of administering a medicament by inhalation which comprises the use by a patient of an inhaler according to claim 1.

23. A method of administering a dry powder inhalation medicament using an inhaler according to Claim 7.

24. A method of treatment of a patient with a respiratory disorder which comprises the administration of a combination of medicaments using an inhaler according to Claim 7.

25. A medicament delivery device (1) substantially as described with reference to the accompanying drawings.

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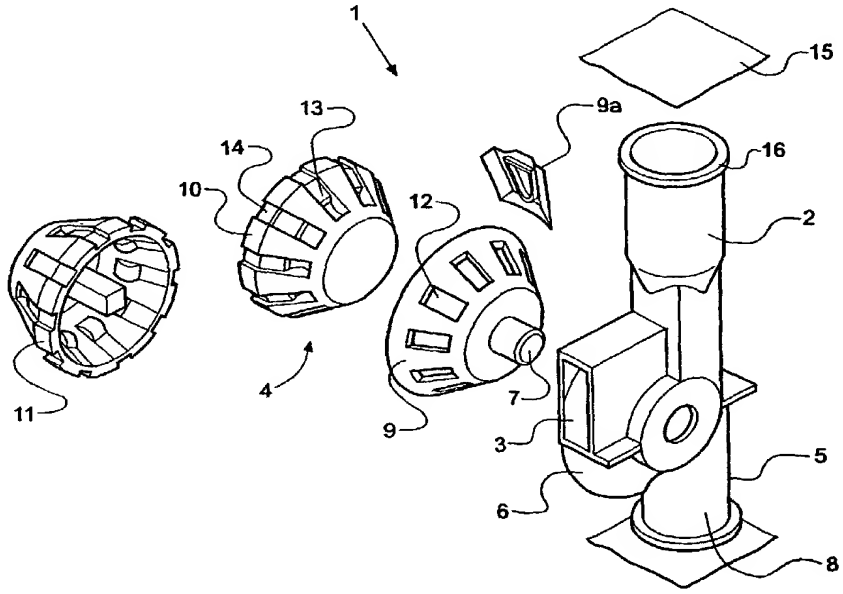
28 June 2001

[Continued on next page]

(54) Title: DELIVERY SYSTEM



(57) Abstract: There is described a medicament delivery device (1) which comprises a medicament reservoir (2), a medicament delivery passage (3) and a metering member (4) adapted to transfer a measured dose of medicament from the medicament reservoir to the delivery passage characterised in that the device is provided with a moisture proof barrier (9). The medicament delivery device is especially suited for use as an inhaler. There is therefore also decribed an inhaler which provides improved airflow for the dispersion of medicament, and a method of treating patients suffering from a respiratory disorder.

WO 00/74754 A3

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

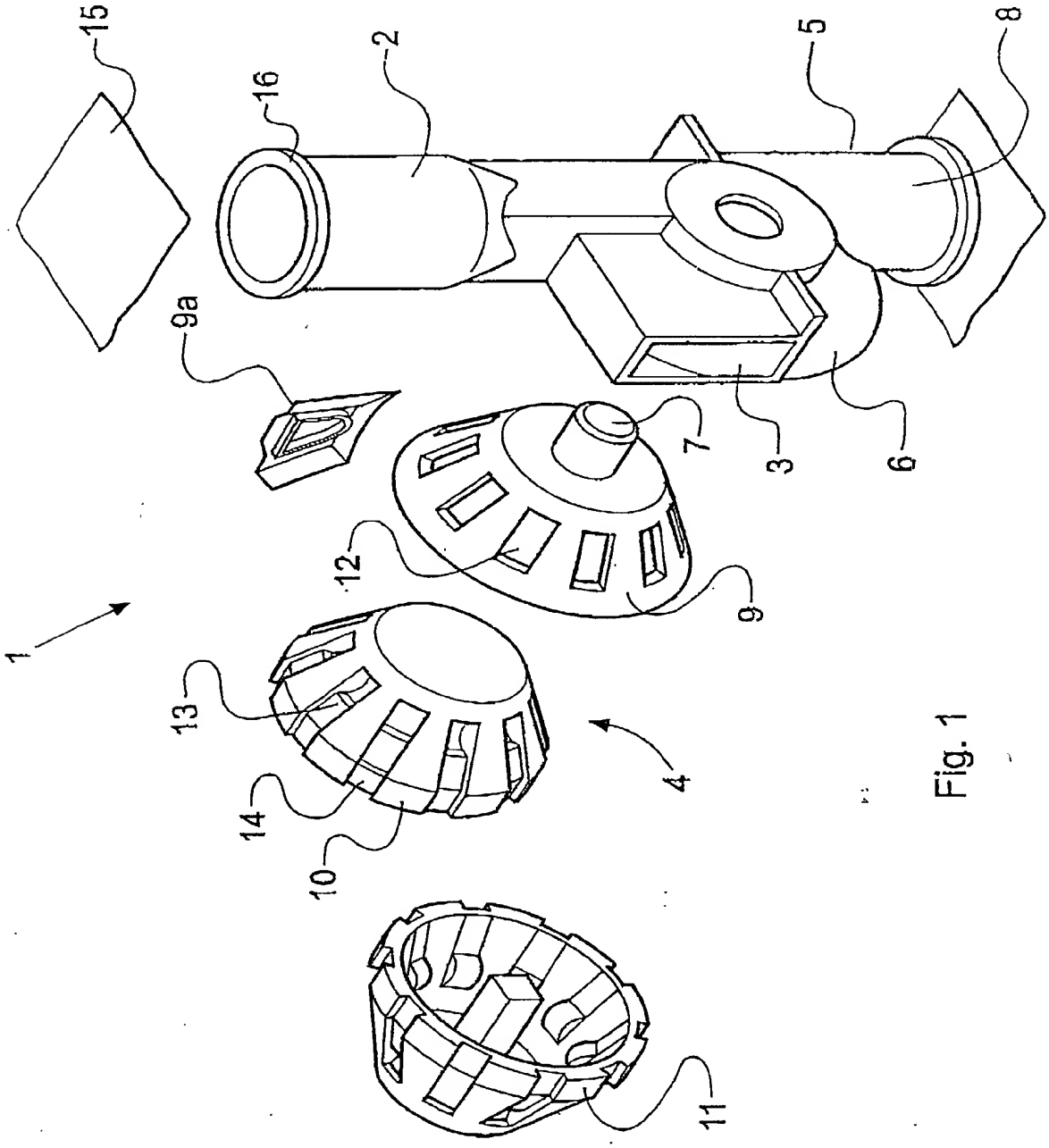
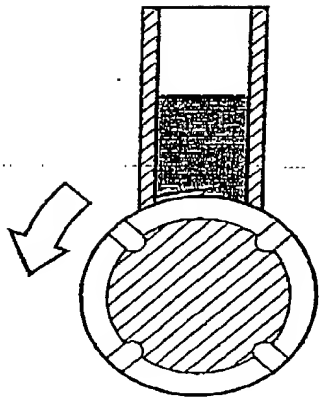


Fig. 1



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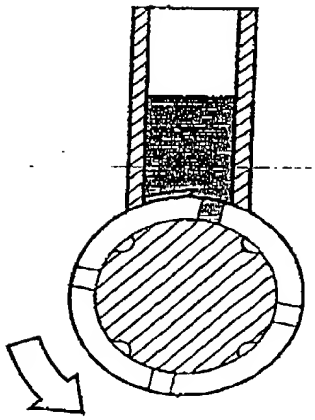

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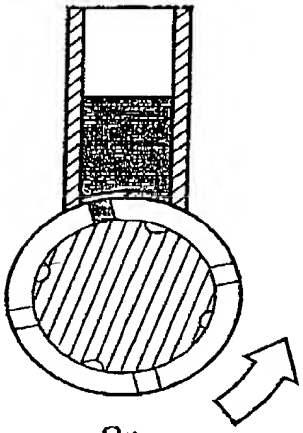

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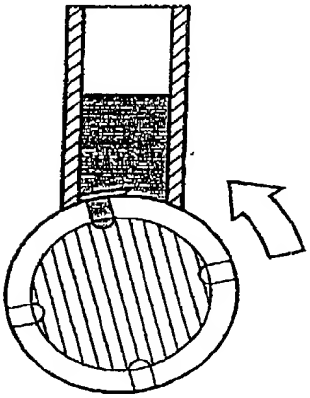

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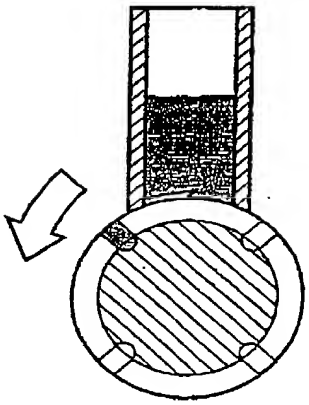

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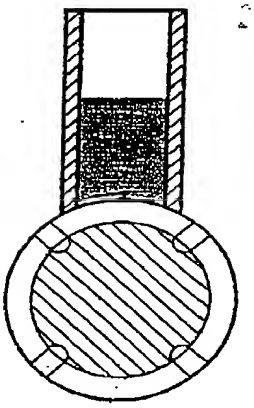

2f

Fig. 2

3/3

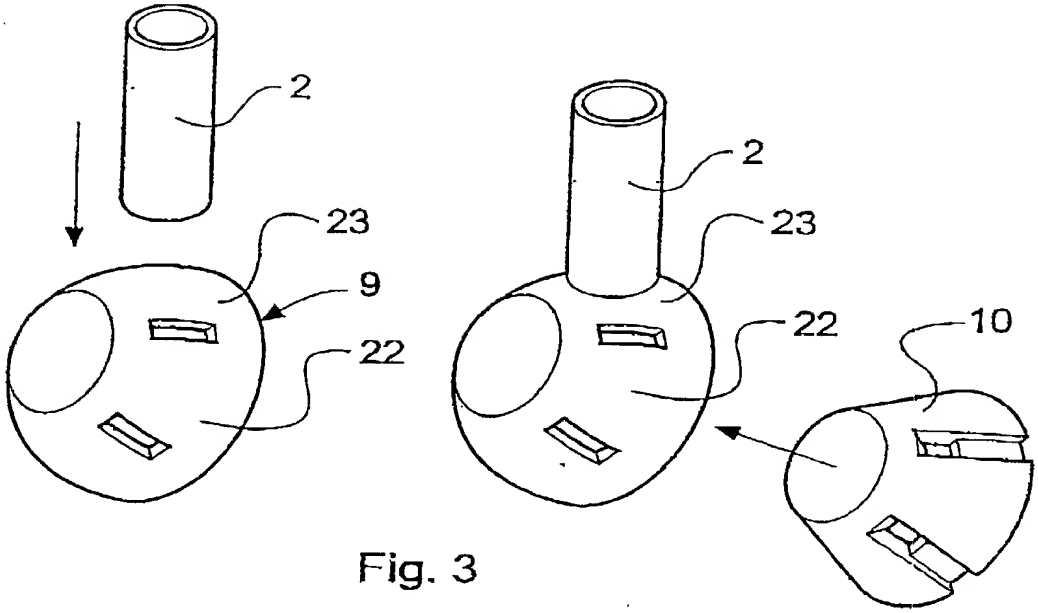

Fig. 3

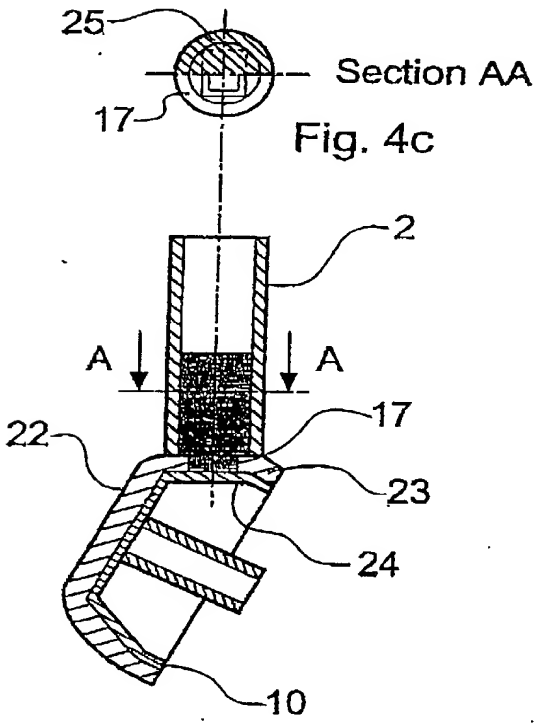

Fig. 4c

Fig. 4a

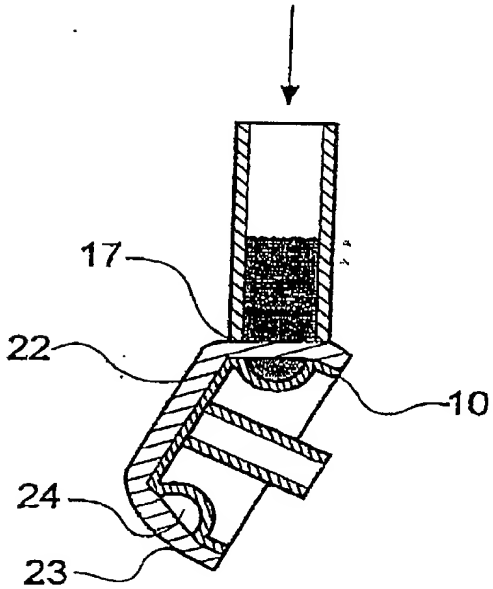

Fig. 4b

Fig. 4

Practitioner's Docket No. 2245/107 ***PATENT***

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is for a national stage of PCT application.

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

Moisture Resistant Inhaler

SPECIFICATION IDENTIFICATION

The specification was described and claimed in PCT International Application No. PCT/GB00/02017 filed on June 5, 2000 and was amended under PCT Article 19 on December 14, 2000.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent.

PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the

same subject matter having a filing date before that of the application(s) of which priority is claimed.

Such applications have been filed as follows.

PRIOR FOREIGN APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 U.S.C. SECTION 119
GB	9913047.8	5 June 1999	yes
GB	9916283.6	13 July 1999	yes

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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Jean M. Tibbetts	43,193
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Alexander J. Smolenski	47,953
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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

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Inventor's signature _____
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Application Information

Title Line One::	Moisture Resistant Inhaler
Total Drawing Sheets::	3
Formal Drawings?::	Yes
Application Type::	Utility
Docket Number::	2245/107

Representative Information

Representative Customer Number::	002101

Continuity Information

This application is a::	371 of
> Application One::	PCT/GB00/02017
Filing Date::	05 June 2000

Prior Foreign Applications

Foreign Application One::	9913047.8
Filing Date::	05 June 1999
Country::	GB
Priority Claimed::	Yes

Foreign Application Two::	9916283.6
Filing Date::	13 July 1999
Country::	GB
Priority Claimed::	Yes